

SAS:jam 6/2/04
PATENT

Attorney Reference Number 6122-54472-01
Application Number 09/788,264

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of the claims in this application:

Listing of Claims:

Claims 1 (currently amended): An interlabial delivery device comprising a pad, wherein the pad is configured to be retained between labia of a subject, and the pad carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent;

wherein the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space, wherein the pad includes a cavity in an external surface of the pad, wherein substantially all the diagnostic or therapeutic agent is contained within the cavity.

Claim 2 (canceled).

Claim 3 (currently amended): The device of claim 2 1, wherein the pad is a highly absorbent non-swelling material.

Claim 4 (currently amended): The device of claim 2 1, wherein the pad is elongated to extend along the interlabial space to frictionally engage the pad against the labia and enable the pad to resist dislodgement.

Claim 5 (canceled).

Claim 6 (previously presented): The device of claim 1, wherein the minor and major portions of the pad have an elliptical cross-section with a major axis, wherein the major axis of the minor portion is less than the major axis of the major portion, and the major axis is of a sufficient size to retain the device substantially completely external to a vaginal orifice.

Claim 7 (original): The device of claim 1, wherein the delivery material includes an

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agent for absorbing odors.

Claim 8 (original): The device of claim 1, wherein the agent is a diagnostic agent.

Claim 9 (original): The device of claim 1, wherein the agent is a therapeutic agent.

Claim 10 (original): The device of claim 1, wherein the delivery device comprises an intravaginal portion and an extravaginal portion, and the intravaginal portion carries the agent to be delivered.

Claim 11 (original): The device of claim 1, wherein the agent is an antibiotic or anti-fungal agent.

Claim 12 (original): The device of claim 1, wherein the agent is a hormone.

Claim 13 (original): The device of claim 1, wherein the agent is a transdermal agent.

Claim 14 (previously presented): The device of claim 1, wherein the agent is a drug in a unit dosage form.

Claims 15-21 (canceled).

Claim 22 (currently amended): A method for administering a drug to a subject, comprising inserting a pad impregnated with the drug into the subject's interlabial space, positioning the pad against the subject's external vaginal orifice, wherein the pad is devoid of corners and flat surfaces, and the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion, wherein both the minor and the major portion are curvilinear in cross-section, and wherein the minor portion facilitates insertion between the subject's labia and retention in the interlabial space; and

retaining the pad in the interlabial space to dispense the drug interlabially, wherein the

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pad includes a recess that extends along an exterior surface of the pad, and in which the drug is placed, wherein compression of the pad compresses the recess to dispense the drug.

Claim 23 (original): The method of claim 22, wherein the pad is elongated and has a uniform cross-section along its entire length, or is tapered along its length.

Claim 24 (previously presented): The method of claim 22, wherein the pad is elongated, and when placed in the interlabial space to dispense the drug, extends completely external to the vaginal orifice.

Claim 25 (original): The method of claim 22, wherein the pad carries a therapeutically effective amount of a medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject.

Claim 26 (previously presented): The method of claim 22, wherein the medicinal agent is an antifungal agent or a hormone.

Claims 27-28 (canceled).

Claim 29 (previously presented): The method of claim 22, wherein the minor and major portions of the pad have a length greater than their width, and the shape of the pad substantially conforms to the interlabial space in which the pad is retained.

Claim 30 (previously presented): The method of claim 29, wherein the pad is held between the labia without adhesive or attachment to a supporting garment.

Claim 31 (previously presented): The method of claim 22, wherein the major portion of the pad has longitudinally extending, opposed, substantially parallel face portions.

Claim 32 (previously presented): The method of claim 22, wherein the minor portion of the pad has longitudinally extending, opposed substantially parallel face portions.

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Claim 33 (previously presented): The method of claim 32, wherein the opposed flat face portions of the pad are substantially parallel.

Claim 34 (previously presented): The method of claim 32, wherein the opposed flat face portions of the pad are substantially convergent.

Claim 35 (previously presented): The method of claim 31, wherein the minor portion of the pad has longitudinally extending, opposed substantially parallel face portions.

Claim 36 (previously presented): The method of claim 35, wherein the opposed flat face portions of the pad are substantially parallel.

Claim 37 (previously presented): The method of claim 36, wherein the opposed flat face portions of the pad are substantially convergent.

Claim 38 (previously presented): The method of claim 22, wherein the minor and major portions of the pad have a shoulder shaped junction.

Claim 39 (previously presented): The method of claim 22, wherein the pad carries a therapeutically effective amount of a medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject to relieve the symptom.

Claim 40 (previously presented): The method of claim 39, wherein the medicinal agent is an anti-microbial or a hormone.

Claim 41 (previously presented): The method of claim 22, wherein the pad includes a cavity in which a medicinal agent is placed prior to positioning the pad.

Claim 42 (previously presented): The method of claim 41, wherein the cavity is compressed between the labia when the pad is positioned.

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Claim 43 (previously presented): The method of claim 42, wherein the cavity communicates with an exterior surface of the pad.

Claim 44 (previously presented): The method of claim 43, wherein the cavity is a recess in an exterior surface of the minor portion of the pad.

Claim 45 (previously presented): The method of claim 44, wherein the pad is elongated, and the cavity extends longitudinally along the pad.

Claim 46 (currently amended): The method of claim 28 22, wherein the method further comprises applying medication intravaginally or perilabially prior to or simultaneously with positioning the pad.